DECLARATION OF CONFORMITY		
MANUFACTURER	DJO FRANCE SAS Centre Européen de Frêt 3 rue de Béthar 64990 Mouguerre, France	
EU AUTHORIZED REPRESENTATIVE	N/A	
PRODUCT	Accessories for Ultrasound and Electrotherapy Devices • Microcurrent Probe • Vacuum Electrodes • Rubber Electrodes • Vacuum Sponges • Pocket Sponges • Vacuum Leadhoses • sEMG Module	
PART NUMBER LIST	TF-FRA-009-3_ Accessories for Ultrasound and Electrotherapy Devices Parts_Rev B	
CLASSIFICATION	Class I	
CONFORMITY ASSESSMENT ROUTE	Annex VII	
GMDN CODE	61169, 35995, 61170, 35751, 10396	
UMDNS CODE	13-775	
WE, THE MANUFACTURER, DJO FRANCE SAS, DECLARE UNDER SOLE RESPONSIBILITY THAT THE ITEM TO WHICH THIS DECLARATION IS RELATED IS IN CONFORMITY WITH: • ALL RELEVANT PROVISIONS OUTLINED IN THE OFFICIAL JOURNAL OF THE EUROPEAN COMMUNITY COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES. THE ITEM COMPLIES WITH ALL RELEVANT PROVISIONS OF THE ANNEX I ESSENTIAL REQUIREMENTS • DIRECTIVE 2011/65/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 8 JUNE 2011 ON THE RESTRICTION OF THE USE OF CERTAIN HAZARDOUS SUBSTANCES IN ELECTRICAL AND ELECTRONIC EQUIPMENT (ROHS-2)		
STANDARDS APPLIED	ISO 13485:2003	Medical Devices – Quality management system – Requirements for regulatory purposes
	EN 60601-1:1990 with A1, A2:1993, A2:1995 and A13:1996	Medical electrical equipment - Part 1: General requirements for safety
	EN 60601-1-2:2001	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
	EN 60601-1-6: 2010 (IEC 60601-1-6:2010)	Medical electrical equipment - part 1-6: general requirements for basic safety and essential performance - collateral standard: usability
	EN 60601-2-10:2001 w/A1: 2001	Medical electrical equipment - Part 2: Particular Requirements for the safety of nerve and muscle stimulators
	EN 980:2008	Symbols for use in the labeling of medical devices
	EN 1041:2008	Information supplied by the manufacturer with medical devices
	EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices
	ISO 10993-1:2009	Biological Evaluation of medical devices – Part 1: General requirements for basic safety and essential performance
	EN 62304:2008	Medical Device Software - Software Life-Cycle Processes
	IEC 62366:2008	Medical devices – Application of usability
	ISO 15223-1:2012	Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements

	MEDDEV 2.7.1 Rev 3	Clinical Evaluation: A Guide for Manufacturers and Notified Bodies
	Uniform Freight Classification Rule 41 / National Motor Freight Classification Item 222	Shipping regulations
NOTIFIED BODY	N/A	
EC CERTIFICATE(S)	N/A	
PLACE OF ISSUE	Vista, CA, USA	
SIGNATURE	SIGNED FOR AND ON BEHALF OF DJO FRANCE SAS,  Name: Daniela Zaczek Title: Regulatory Affairs Manager Date: August 20, 2018	

DECLARATION OF CONFORMITY		
MANUFACTURER	DJO FRANCE SAS Centre Européen de Frêt 3 rue de Béthar 64990 Mouguerre, France	
EU AUTHORIZED REPRESENTATIVE	N/A	
PRODUCT	Accessories for Ultrasound and Electrotherapy Devices • Anal/Vaginal Probes	
CLASSIFICATION	Class IIa	
CONFORMITY ASSESSMENT ROUTE	Annex II – Full Quality Assurance	
GMDN CODE	36050	
UMDNS CODE	13-775	
WE, THE MANUFACTURER, DJO FRANCE SAS, DECLARE UNDER SOLE RESPONSIBILITY THAT THE ITEM TO WHICH THIS DECLARATION IS RELATED IS IN CONFORMITY WITH: • ALL RELEVANT PROVISIONS OUTLINED IN THE OFFICIAL JOURNAL OF THE EUROPEAN COMMUNITY COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES. THE ITEM COMPLIES WITH ALL RELEVANT PROVISIONS OF THE ANNEX I ESSENTIAL REQUIREMENTS • DIRECTIVE 2011/65/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 8 JUNE 2011 ON THE RESTRICTION OF THE USE OF CERTAIN HAZARDOUS SUBSTANCES IN ELECTRICAL AND ELECTRONIC EQUIPMENT (ROHS-2)		
STANDARDS APPLIED	ISO 13485:2003	Medical Devices – Quality management system – Requirements for regulatory purposes
	EN 60601-1:1990 with A1, A2:1993, A2:1995 and A13:1996	Medical electrical equipment - Part 1: General requirements for safety
	EN 60601-1-2:2001	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
	EN 60601-1-6: 2010 (IEC 60601-1-6:2010)	Medical electrical equipment - part 1-6: general requirements for basic safety and essential performance - collateral standard: usability
	EN 60601-2-10:2001 w/A1: 2001	Medical electrical equipment - Part 2: Particular Requirements for the safety of nerve and muscle stimulators
	EN 980:2008	Symbols for use in the labeling of medical devices
	EN 1041:2008	Information supplied by the manufacturer with medical devices
	EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices
	ISO 10993-1:2009	Biological Evaluation of medical devices – Part 1: General requirements for basic safety and essential performance
	EN 62304:2008	Medical Device Software - Software Life-Cycle Processes
	IEC 62366:2008	Medical devices – Application of usability
	ISO 15223-1:2012	Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements
	MEDDEV 2.7.1 Rev 3	Clinical Evaluation: A Guide for Manufacturers and Notified Bodies
	Uniform Freight Classification Rule 41 / National Motor Freight Classification Item 222	Shipping regulations

NOTIFIED BODY	BSI Group Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP Telephone: +44 (0) 1908 814844 Fax: +44 (0) 1908 814924 N/O No: 0086
EC CERTIFICATE(S)	EC Certificate #: CE 681250 Issue date: 2018-07-27 Expiration date: 2019-01-23
PLACE OF ISSUE	Vista, CA, USA
SIGNATURE	SIGNED FOR AND ON BEHALF OF DJO FRANCE SAS,  Name: Daniela Zaczek Title: Regulatory Affairs Manager Date: August 20, 2018